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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/886,327

06/21/2001

James Allen McEwen

1077-023-PWH

6889

60597

7590

11/15/2006

PATRICK W. HUGHEY

P.O. BOX 6553

PORTLAND, OR 97228

EXAMINER

BUI, VY Q

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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**MAILED**

**NOV 15 2006**

**Group 3700**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/886,327  
Filing Date: June 21, 2001  
Appellant(s): MCEWEN, JAMES ALLEN

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Patrick W. Hughey  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 12/10/2004 appealing from the Office action mailed 01/05/2004.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1, 2, 5, 6, 8-13, 15-17, 19, 21 and 22.

Claims 3, 4, 7, 14 and 18 have been canceled.

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

Art Unit: 3734

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Claims 1-2, 5-6, 11-13, 15-17, 19, and 21 - 22 stand rejected under 35 USC § 103(a) as obvious over Smith & Nephew Richards in view of Smith et al-4,650,475.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

4,650,475

Smith et al.

3-1987

Smith and Nephew Richards' cuff (3 pages cited before and now attached for convenient reference)

**(9) Grounds of Rejection**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 2, 5-6, 11-13, 15, 17 and 22 are rejected under 35 U.S.C. 103(a) as obvious over SMITH and NEPHEW RICHARDS reference in view of SMITH et al.-4,650,475.

As to claims 1, 2, 6, 12 and 15, SMITH and NEPHEW RICHARDS discloses a pair of an associated sleeve and an associated cuff packed together. The cuff has a first color code or first color mark or first color indicium to indicate the size of the cuff. SMITH and NEPHEW RICHARDS reference does not explicitly disclose a second color code/second mark/second indicium on the sleeve. However, Smith et al.-4,650,475 (Fig. 1; col. 1, lines 50-52; col. 2, lines 4048) discloses a pair of cuff 24 and sleeve 30 having same color codes for matching the two together. In view of Smith-'475, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide a code for matching a pair of cuff and sleeve of SMITH and NEPHEW RICHARDS so that one can correctly match the two of cuff and the associated sleeve quickly.

As to claims 13 and 22, SMITH and NEPHEW RICHARDS discloses substantially the claimed invention. Except for a sleeve sized as recited in the claims. However, it would have been an obvious matter of design choice to modify the size of the sleeve as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

As to claims 5 and 11, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee discloses monitoring an inflation pressure of the cuff (page 1, precaution section, item 2). Inherently, there must be an instrument for pressurizing or inflating the cuff.

Art Unit: 3734

As to claim 17, as admitted by the Applicant in the "Appeal Brief", "Argument" section (page 6 of 14, first paragraph and page 7 of 14, second paragraph), "Smith & Nephew Richards packs together a cuff and a sleeve" into a pair/package.

2. Claims 16, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee.

Regarding claims 16, 19, 21, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee does not disclose the stockinette sleeve applying a pressure less than a predetermined pressure of about 2 mmHg on the limb. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make experiments to determine the optimum value of a predetermined pressure of 2 mmHg since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

#### ***Allowable Subject Matter***

Claims 8-10, 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **(10) Response to Argument**

As to the argument about the rejection of the claims, please see the rejections above.

Art Unit: 3734

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.


For the above reasons, it is believed that the rejections should be sustained. Respectfully submitted,



Vy Q Bui

P.E. AU 3734

Conferees:

  
Angela Sykes

SPE TC 3700

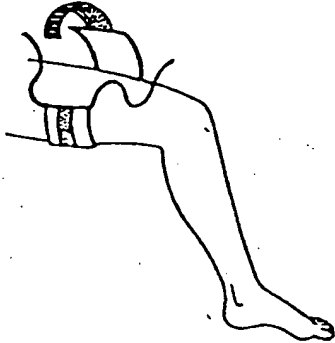
  
Michael Hayes

SPE AU 3734

  
FREDERICK R. SCHMIDT  
DIRECTOR  
TECHNOLOGY CENTER 3700

# RICHARDS DISPOSABLE TOURNIQUET CUFFS

## IMPORTANT GENERAL USE GUIDELINES



Richards Disposable Cuffs are sterile, disposable, patient ready tourniquet cuffs for use in both elective and emergency surgical procedures where interruption of blood flow and clear visualization of the operative site is indicated.

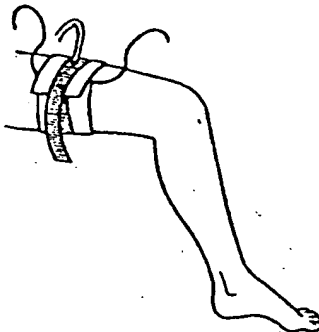
### IMPORTANT:

Tourniquets should be applied with full and adequate knowledge of its intended use and awareness of all possible complications.

Extreme care should always be exercised in application and usage. All final decisions regarding the use of the tourniquet are the responsibility of the physician in charge.

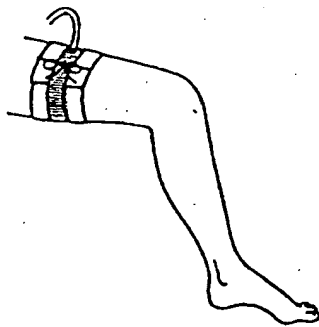
### APPLICATION:

1. The tourniquet should be applied as far proximally as possible, on either the upper or lower extremity, at the maximum circumference of the limb.
2. Select a cuff large enough to have a suggested three-to-four inch overlap and avoid rotary movement after application.
3. Prior to application, wrap the area with a stockinette sleeve.
4. Avoid any wrinkles in the stockinette sleeve or cuff, secure Velcro closure and tie.
5. Securely connect (single port, or dual port) inflation line to inflation system.



### PRECAUTIONS:

1. Exercise extreme care when using tourniquets of any type. Minimum pressure and application time should be used in all procedures.
2. Carefully monitor set inflation pressure during the entire procedure to assure the desired pressure is being accurately maintained.
3. To avoid chemical burns to the patient, take care that no caustic solutions are allowed to run under the cuff.
4. Richards Disposable Cuffs are designed for single patient use, and the manufacturer does not recommend re-processing or re-sterilization.



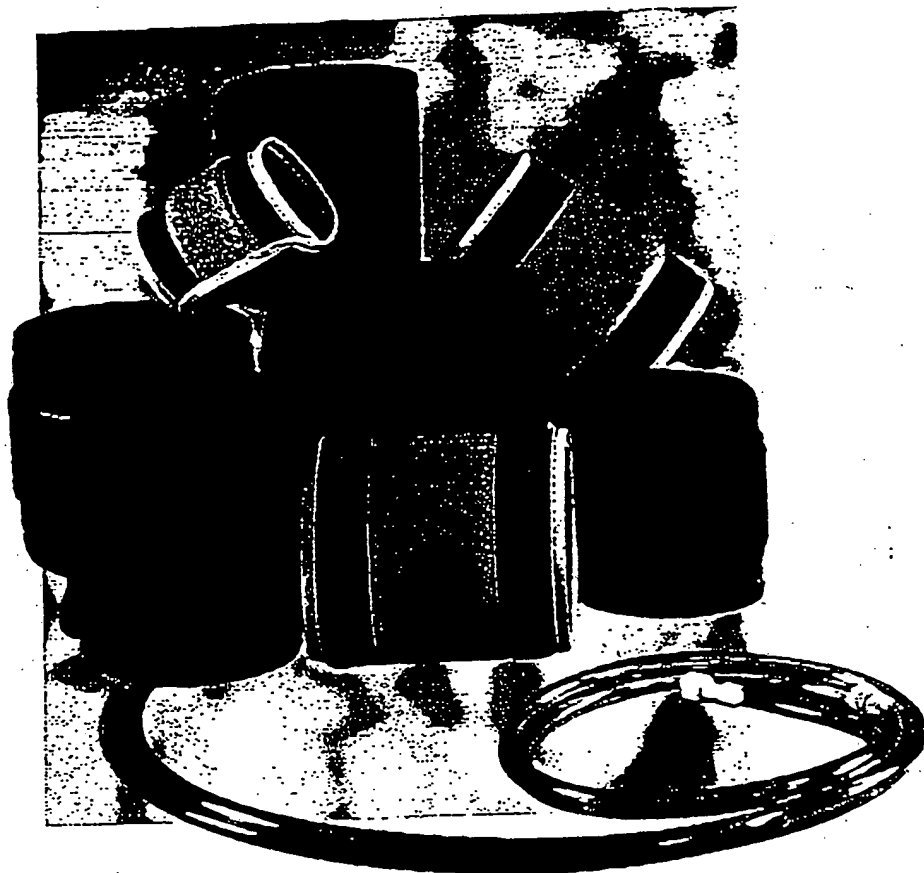
**Smith & Nephew Richards Inc.**

1450 Brooks Rd., Memphis, TN 38116 U.S.A.  
901-396-2121, For information: 1-800-821-5700  
For orders and order inquiries: 1-800-238-7538

**Smith+Nephew**



# REDUCE THE RISK!



## RICHARDS DISPOSABLE CUFFS

DISPOSABLE, STERILE, AND READY-TO-USE, tourniquet cuffs from Smith & Nephew Richards help reduce the risk of patient cross-contamination by providing a sterile product for every use. In addition, disposability eliminates expensive, time-consuming washing and terminal-processing. The sterile fill lines also maintain the sterilization field.



Made of a soft broadcloth which helps reduce cuff creasing, the Richards Disposable Cuffs are available with stockinette sleeves to provide a cushion of protection between the tourniquet cuff and the patient's skin.

A wide range of sizes and styles are offered to fit the patient and the procedure. Color-coded by size to facilitate set-up time and correct sizing, Richards Disposable Cuffs are efficient, economical alternatives to reusable cuffs and fit most manual and automatic tourniquet systems. For more information, ask your Smith & Nephew Richards Representative or call 1-800-821-5700.

# RICHARDS DISPOSABLE CUFFS

## CATALOG INFORMATION

### Catalog No.

1 Fill Line	2 Fill Lines	Application	Size	Color	Case Qty.*
7010-7000	7010-7001	Infant	8"	Light Blue	12
7010-7002	7010-7003	Child	12"	Plum	12
7010-7004	7010-7005	Child (Long)	15"	Gray	12
7010-7006	7010-7007	Standard Arm	18"	Red	18
7010-7008	7010-7009	Standard Leg	24"	Yellow	18
7010-7010	7010-7011	Long Leg	34"	Blue	18
7010-7012	7010-7013	Super Cuff	44"	Green	12
7010-7014**	7010-7015***	BB Double Bladder	20"	Navy Blue	12
7010-7016**	7010-7017***	BB Double Bladder	26"	Orange	12

40" fill line, luer connector, and stockinette sleeve standard on each tourniquet.

## VARIETY PACKS

Catalog No.	Description	Size	Qty.
7010-7080	Single Fill Line	12"	2
		18"	3
		24"	3
		34"	3
		44"	1
7010-7081	Dual Fill Line	12"	2
		18"	3
		24"	3
		34"	3
		44"	1

## FILL LINES

Catalog No.	Description	Case Qty.
7010-7070	60" Sterile Fill Line	12
7010-7071	60" Sterile Fill Line	18

\*Product must be ordered in multiples of the case quantity. (Minimum order, one case. Ask your sales representative about smaller case quantities.)

\*\*One fill line per bladder.

\*\*\*Two fill lines per bladder.

For more information, contact your Smith & Nephew Richards Representative or call us at 1-800-821-5700.

**Smith & Nephew Richards**

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page 3/3,